



# KAISER PERMANENTE®

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<b>AUTHOR:</b>	<b>PREVIOUS NUMBER:</b>
<b>OWNER:</b>	<b>CHANGE NUMBER:</b>

## Corrective Action Preventive Action Plan

**Purpose** This document will serve to describe the process of creating and documentation of corrective action preventative action plans. These plans will provide a guideline toward process improvement and tools to measure that improvement.

**Policy** Upon identification of an area needing improvement, an investigation must be performed to review the best way to achieve that corrective action.

**Definition** Corrective Action

- Actions taken to fix an existing condition.
- Usually the condition is brought to light via a QIM report, inspection finding, or other problem.

Preventive Action

- Actions taken to avoid a potential problem, QIM or citation.
- These conditions may come to light usually as a result of quality tools showing a trend in an unfavorable direction or a drift in performance or controls are recognized, before there is any actual problem.

**Procedure**

Follow the steps below to complete the <i>Process Improvement Documentation</i> form	
Section	Action
Corrective Action or Preventive Action	Based on the definitions above, select if this Process Improvement is based on a corrective action or preventive action.  Check the appropriate box.
Source	<u>Corrective Action</u> : List the citation number, the citing agency and date of the citation or non-conformance. This can be from an internal audit, external audit or from QIM reports.
	<u>Preventive Action</u> : List the trend of existing data, or reason for making a change. List dates and documents that were reviewed to access the potential problem.

## Corrective Action Preventive Action Plan, Continued

Item identified	<ul style="list-style-type: none"> <li>Clearly (and briefly) identify the policy, process, procedure, form or other item that is the focus of the process improvement.</li> <li>Record the area or category targeted for this process improvement.</li> </ul>
Evaluation	Review the descriptions in the table, and select (mark) the one that best applies to this corrective or preventive action.
Investigate	Indicate how you can obtain or collect data to move this project toward resolution. Examples would be to perform a root cause, solicit input from all staff, review patient charts, etc.
Analysis	<p>This would require a lab manager or designee to review the data collected so far, and to decide if this should be continued as a corrective action or preventive action project. Items to consider:</p> <ul style="list-style-type: none"> <li>How important is this to our department, facility or hospital?</li> <li>Are there resources to perform this action?</li> <li>Should this be performed at a later time? IF so when? Is it safe or prudent to wait on this issue?</li> <li>Is something else going to be impacted (negatively or positively) by this project? If so list.</li> </ul>
Action Plan	<p>Action Items:</p> <ul style="list-style-type: none"> <li>List the action items you have identified that need to be completed for this corrective or preventive action.</li> <li>Assign a responsible person to oversee each item listed.</li> <li>Determine start dates and completion dates for each action item.</li> <li>As the action items are completed, record the actual start and completion dates for each item.</li> <li>Add comments if applicable.</li> </ul> <p>Equipment</p> <ul style="list-style-type: none"> <li>List the equipment that may be needed for the completion of this corrective or preventive action project, if applicable.</li> <li>List equipment model number.</li> <li>List the KP IR number, if applicable for the equipment.</li> <li>Add comments as needed for each piece of equipment that is needed or used for this project.</li> </ul>

## Corrective Action Preventive Action Plan, Continued

	Measurement	
	<ul style="list-style-type: none"> <li>List the method of measurement that will be used to measure or track the results of this project.</li> <li>List the frequency of sampling, the number of samples to be taken for this project. Depending on the project and the frequency of events, the sampling could take days or several months.</li> <li>Document the duration of tracking the measurements. This would be your estimation of how long it would take to have an appropriate number of events that could be measured.</li> <li>List comments as needed.</li> </ul>	
	Other Items	
	<ul style="list-style-type: none"> <li>List policies, processes, procedures, forms or other documents that may need to be revised. Complete the table the same way as the Action item table.</li> <li>Determine if training is required. Complete the table the same way as the Action item table</li> <li>List any other areas that may need to be developed as a result of this project.</li> </ul>	
Conclusion	<p>Discuss your decision to implement a change or other action, based on the action plan above.</p> <ul style="list-style-type: none"> <li>Describe the decision made after this Process Improvement             <ul style="list-style-type: none"> <li>Did it result in change?</li> <li>Will the sop or process change?</li> <li>Is training needed? Who needs to be trained?</li> </ul> </li> <li>How will this action actually improve the process involved?</li> </ul>	
	<ul style="list-style-type: none"> <li>Based on the conclusion, check the box that best describes the next step for this process</li> </ul>	
	Issue completely resolved no further need to track.	<ul style="list-style-type: none"> <li>Imply that the purpose of the process improvement was satisfactorily addressed and that no further issues are pending.</li> </ul>
	Issue resolved after modification of improvement tool.	<ul style="list-style-type: none"> <li>Imply that the issue was not satisfactorily resolved, but could be after a modification the improvement process. This could be a rewording of the process, or adding more direction to the action plan, etc.</li> </ul>

## Corrective Action Preventive Action Plan, Continued

	Audit again for _____ months starting	<ul style="list-style-type: none"> <li>• Imply that the improvement process is acceptable as planned, but that the improvement is taking longer than the selected time frame allotted to the improvement process.</li> </ul>
	Issue improved but still needs to be audited for _____ more months.	<ul style="list-style-type: none"> <li>• Imply that the process was improved, but that it would benefit if audited for an extended time period.</li> </ul>
	No affect on the issue, re-review issue and perform root cause to determine methods to use for improvement.	<ul style="list-style-type: none"> <li>• Imply that the Process Improvement selected was not successful. This will require further root cause analysis and more brainstorming by staff knowledgeable in this process.</li> <li>• The Process Improvement process will need to be performed again with the new improvement.</li> </ul>
Signatures	At the completion of the process, successful or not, this plan is approved by the Transfusion Service manager, Laboratory Operations Director and Transfusion Service Medical Director.	
Implementation date	Document the date the corrective or preventive action was implemented.	
Post-Implementation assessment	Record the date for the post-implementation assessment. This should be determined at the time of implementation.	
	Mark the box that best describes the results of the post-implementation assessment	
	Change is working as expected. No further tracking needed.	The new policy, process, procedure, form or other document or action is giving the desired results, and has corrected the original problem. No further tracking is needed at this time.

## Corrective Action Preventive Action Plan, Continued

	Change is working well, needs minor modification	The change is achieving the desired result, but some part of the process needs minor modification(s). Proceed with the modification, and determine if further tracking needs to be performed.
	Change is not working, re-evaluate this corrective preventive action plan and suggest new plan based on root cause analysis or other method of analysis.	The change did not result in the desired result. This corrective or preventive action plan needs to be re-evaluated with a new root cause analysis or other equivalent analytic tool.
Signature	The Transfusion Service manager or designee signs and dates the final form indicating the whole process has been reviewed and all comments are correct.	
Records	This document is stored in the Transfusion Service per current record retention guidelines.	

**Controlled Documents**

- Process Improvement Documentation form

**Uncontrolled Documents**

- Fung, Mark K. Ed. Technical Manual, 18th Ed. AABB, 2014
- AABB Standards, current ed.
- CAP Requirements, checklist, current ed.

**Authors:**

All SCPMG Transfusion Services Managers  
 Regional Blood Bank Compliance Officer

**Distribution**

All SCPMG Transfusion Services

## Corrective Action Preventive Action Plan, Continued

Reviewed and approved by:  
Virginia Tyler

12/20/2005

Virginia Vengelen-Tyler, MBA, MT,ASCP(SBB), CQA(ASQ)  
Regional Blood Bank Compliance Officer

Date

Signature Collected Electronically

January 5, 2011

Adriana A. Bedoya, M.D. FCAP, FASCP  
Medical Director- San Diego –SA

Date

Signature Collected Electronically

August 8, 2005

Gary Gochman, MD, Medical Director –Tri-Central SA

Date

Signature Collected Electronically

August 4, 2010

Jeffrey D. Shiffer, MD. Medical Director –San Fernando  
Valley SA

Date

Signature Collected Electronically

August 2, 2005

Joseph Thompson, MD. Medical Director –Metropolitan SA

Date

Signature Collected Electronically

August 15, 2005

David Huebner-Chan, MD. Medical Director –Orange County  
SA

Date

Signature Collected Electronically

December 19, 2005

Dong Quach, MD. Medical Director –Inland Empire SA

Date

Signature Collected Electronically

September 14, 2005

Ramesh Doshi, MD. Medical Director- Tri-Central SA

Signature Collected Electronically

August 4, 2005

Brian Platz, MD, Medical Director- West Los Angeles

Date

## Corrective Action Preventive Action Plan, Continued

### DOCUMENT HISTORY PAGE

Effective Date: December 20, 2005

Change type: new, major, minor etc.	Changes Made to Document – Describe	Signature responsible person/Date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ Date	Date change Imp.
New					
Minor	1. Added Irvine 2. Added Work Place Safety No version change needed	Ginny Tyler 02/19/08	N.A.	N.A.	

IMP = Implemented

<b>MasterControl History of Change:</b>		
<b>Change type: new, major, minor etc.</b>	<b>Version #</b>	<b>Description of Change</b>
Minor	1	Reformatted Changed supervisor to Lab Manager
Minor	2	Removed references to donor centers and specified record retention. Updated Controlled and Uncontrolled documents. Updated title from “Preventive Action Corrective Action Plans”



## Signature Manifest

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Revision: 2

Title: Corrective Action Preventive Action Plans

All dates and times are in Pacific Standard Time.

### CAPA-minor

#### Minor Change Request

Name/Signature	Title	Date	Meaning/Reason
Helen Noriega (S688941)	ASST DIR AREA LAB		
Ann Sintef (G938509)	Regional Blood Bank Compliance	27 Jan 2017, 04:01:14 PM	Approved

#### RL TS LM Collaboration

Name/Signature	Title	Date	Meaning/Reason
Lynne Sands (I924027)	LEAD CLS		
Monica Flores (K112468)	LIS Application Specialist		
Armineh Amirian (K230074)	LIS Application Specialist		
Angela V Test user (MCUSER4)			
Joanne Jocom (P170170)	MGR AREA LAB		In Process
Jennifer Aidikoff (Q382370)	Blood Bank Manager		
Helen Noriega (S688941)	ASST DIR AREA LAB		
Jane Byrne (Y784700)	MGR AREA LAB		
Rika Wakelin (C159483)	Manager	27 Jan 2017, 05:12:46 PM	Complete & Quit
Gloria Escobedo (K255208)	AREA LAB MGR	30 Jan 2017, 02:19:02 PM	Complete
Jennifer Zalamea (P303429)	MGR AREA LAB	31 Jan 2017, 02:55:24 PM	Complete
Angela Varela (P384373)	MGR AREA LAB	10 Feb 2017, 05:07:49 PM	Complete
Alejandra Salazar (K233690)	MGR AREA LAB	13 Feb 2017, 04:52:40 PM	Complete
Cynthia Calderon (A088729)	MGR AREA LAB	16 Feb 2017, 01:23:10 PM	Complete
Jeremiah Ocampo (K607321)	MGR AREA LAB	01 Mar 2017, 01:54:46 PM	Complete
Brevet. Dao (Y363374)	MGR AREA LAB	02 Mar 2017, 11:18:29 AM	Complete
Richard Ulep (H355837)	MGR AREA LAB	06 Mar 2017, 08:32:37 AM	Complete
Nancy Messiah (O126459)	MGR AREA LAB	07 Mar 2017, 09:49:45 AM	Complete
Rogelio AngLee (K149343)	MGR AREA LAB	08 Mar 2017, 11:57:09 AM	Complete & Quit
Ann Sintef (G938509)	Regional Blood Bank Compliance	14 Mar 2017, 01:26:03 PM	Complete

#### Final Approval

Name/Signature	Title	Date	Meaning/Reason
Nancy Messiah (O126459)	MGR AREA LAB	14 Mar 2017, 01:45:27 PM	Approved
Jeremiah Ocampo (K607321)	MGR AREA LAB	14 Mar 2017, 06:14:49 PM	Approved
Jennifer Zalamea (P303429)	MGR AREA LAB	16 Mar 2017, 01:45:04 PM	Approved
Gloria Escobedo (K255208)	AREA LAB MGR	21 Mar 2017, 10:57:26 AM	Approved
Brevet. Dao (Y363374)	MGR AREA LAB	22 Mar 2017, 09:52:09 AM	Approved
Rogelio AngLee (K149343)	MGR AREA LAB	29 Mar 2017, 08:19:03 AM	Approved
Angela Varela (P384373)	MGR AREA LAB	12 Apr 2017, 02:50:07 PM	Approved
Jennifer Aidikoff (Q382370)	Blood Bank Manager	13 Apr 2017, 11:04:29 AM	Approved
Duane Doerr (T865608)	MGR AREA LAB	17 Apr 2017, 07:42:12 AM	Approved
Jane Byrne (Y784700)	MGR AREA LAB	21 Apr 2017, 09:00:28 AM	Approved

Alejandra Salazar (K233690)	MRG AREA LAB	21 Apr 2017, 03:56:16 PM	Approved
Cynthia Calderon (A088729)	MGR AREA LAB	24 Apr 2017, 04:29:44 PM	Approved
Lynne Sands (I924027)	LEAD CLS	17 May 2017, 10:27:43 AM	Approved
Patricia Jasper (A110687)	CLINICAL LAB SCIENTIST-Area LM	06 Jun 2017, 04:11:49 PM	Approved
Ann Sintef (G938509)	Regional Blood Bank Compliance	09 Jun 2017, 03:47:36 PM	Approved

### Select Effective Dates

Name/Signature	Title	Date	Meaning/Reason
Helen Noriega (S688941)	ASST DIR AREA LAB		
Ann Sintef (G938509)	Regional Blood Bank Compliance	09 Jun 2017, 03:48:17 PM	Approved

### Quick Approval

### Approve Now

Name/Signature	Title	Date	Meaning/Reason
Ann Sintef (G938509)	Regional Blood Bank Compliance	16 Jun 2017, 02:35:35 PM	Approved